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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,001	12/20/2001	Kenneth E. Palmer	00801.0179.CPUS01	5532

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/038,001

Applicant(s)

PALMER ET AL.

Examiner

Gerald G Leffers Jr., PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/21/2002.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group I (claims 1-26) in the response filed 12/15/2003 is acknowledged. Claims 1-29 are pending, with claims 27-29 withdrawn from consideration as being directed to a nonelected invention.

### ***Information Disclosure Statement***

Receipt is acknowledged of an information disclosure statement, filed 6/21/2002. The signed and initialed PTO Form 1449 has been mailed along with this action.

### ***Sequence Compliance***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers and which are not present in the computer readable format (CRF) or the paper sequence and for which no attorney statement was filed. These sequences include **the peptide motifs on page 4 of the instant application**. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

### ***Double Patenting***

Applicant is advised that should claim 12 be found allowable, claim 16 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 12 and 16 each are drawn to the same Markush group of histone proteins, each of which comprises the characteristics of being targeted to the nucleus and being capable of condensing nucleic acids.

Applicant is advised that should claim 22 be found allowable, claim 26 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claims 22 and 26 each are drawn to the same Markush group of histone

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proteins, each of which comprises the characteristics of being targeted to the nucleus and being capable of condensing nucleic acids.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Each of the claims is directed to a polynucleotide capable of eliciting an immunization reaction in a eukaryotic host to a peptide or polypeptide where the polynucleotide encodes the peptide or polypeptide, contains undefined "elements" of a virus capable of rolling circle replication and the peptide or polypeptide is capable of expression in the eukaryotic host. As written, the claims reasonably be read broadly to encompass on any virus expressing any of its own proteins in a eukaryotic host to generate any type of immune response where the virus is capable of rolling circle replication (e.g. a porcine circovirus). Thus, the claims read on products of nature and do not necessarily show the "hand of man". Therefore, the claims read on nonstatutory subject matter.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 17 are vague and indefinite in that the metes and bounds of the phrase "capable of eliciting an immunization reaction in an eukaryotic host" are unclear. It is unclear whether the term "immunization reaction" specifies that the host necessarily become immunized against the peptide or polypeptide (e.g. neutralizing antibodies, etc.) or whether any type of immune response (e.g. activation of B-cells, T-cells, non-specific activation of macrophage or induction of cytokines associated with an immune response) would satisfy the claim limitation. It would be remedial to amend the claim language to clearly indicate what level of immune response is required to satisfy the limitation intended by the phrase "capable of eliciting an immunization reaction in an eukaryotic host".

Claims 1 and 17 recite the limitation of "elements of a viral genome which is capable of rolling circle replication". The specification does not adequately define the term "elements" as it relates to the minimum requirements needed to meet the cited limitation. For example, is the term limited to some part of the viral genome that is required for rolling circle replication? Does the term encompass other "elements" of the virus, such as promoters that aren't directly involved in rolling circle replication? Can the claims be read so broadly so as to encompass any di-nucleotide sequence obtainable from a virus that can undergo rolling circle replication? It would be remedial to amend the claims to explicitly state what constitutes an "element" of such a virus.

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Claim 1 is vague and indefinite in that the metes and bounds of part (c) are unclear. Specifically, it is unclear how a peptide or polypeptide can "express" themselves. It appears that part (c) may be meant to specify that the polynucleotide is capable of expressing the peptide or polypeptide in the eukaryotic host.

Claim 5 is vague and indefinite in that there is no clear and positive prior antecedent basis for the term "said first virus" in claim 4, upon which claim 5 is dependent.

Claim 6 is vague and indefinite in that the metes and bounds of the phrase "operatively linked 5' to a promoter are unclear. Usually, promoters are operatively linked at their 3' end to coding sequences, and not the other way around.

Claim 7 is vague and indefinite in that the metes and bounds of the phrase "a specified cell or tissue type" are unclear. What are the criteria that one uses to determine that a particular tissue or cell is "specified"? How can someone know whether the cell type they have chosen to practice the claimed invention necessarily meets the limitation of being "specified"?

Claim 8 is vague and indefinite in that it is unclear what is intended by the term "ancillary protein". The specification teaches that a protein can be "ancillary" in at least two different ways (e.g. with regard to enhancing immunization or with regard to rolling circle replication). The specification does not appear to delineate between these two distinct possibilities, and does not appear to limit the phrase to just these two possibilities. Read broadly, the claim could be interpreted to encompass any other functionality which one might associate with a protein. It would be remedial to amend the claim to clearly indicate in which way the additional protein is "ancillary".

*Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 13, 15, 17-19, 21, 23 & 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Poet et al (U.S. Patent No. 6,287,856; see the entire patent).

Poet et al teach DNA vaccines comprising components of different members of the family Circoviridae (e.g. chicken anemia virus-CAV, porcine circovirus-PCV and beak and feather disease virus-BFDV). Poet et al teach their invention comprises vaccines comprising circoviral nucleic acids (DNA and RNA) where, when administered to a subject, the vaccines can induce a protective immune response against the virus (e.g. column 3, lines 55-65). Poet et al teach that these nucleic acid vaccines include embodiments where the entire genome is present and expresses one or more of the circoviral polypeptides (e.g. column 7, lines 35-45). In certain embodiments, the entire virus can be transiently expressed via the operative linkage of the encoding sequences to a heterologous promoter (e.g. a CMV promoter/enhancer; column 8, lines 48-55; Example 5). The specification teaches there is significant identity between the capsid proteins and the highly conserved sequences of protamines (e.g. a large number of

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arginine and lysine residues), which are recognized DNA binding proteins (e.g. column 3, lines 50-55).

Packaging of the viral genome into the viral capsid would necessarily be expected to result in compaction of the genomic DNA as this is a normal function of DNA packaging for viruses. Further, one necessarily expect that not all of the circovirus proteins are equally antigenic. Thus, it is reasonable to expect that the inclusion of more than one viral protein in the compositions taught by Poet et al would encompass embodiments where one protein increases the antigenic response as compared to the same construct not expressing that protein.

Claims 1-9, 11, 13, 15, 17-19, 21, 23 & 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Noteborn et al (Gene, Vol. 223, Nos. 1-2, pages 165-172; only the Abstract is provided with this action, the entire document is on order and will be included in any subsequent action on the merits).

Noteborn et al teach chicken anemia virus (CAV) strains having mutated enhancer/promoter regions that have reduced ability to replicate and cytopathogenicity (see the entire abstract). Noteborn et al teach the construction and use of plasmid constructs encoding the CAV genome where the promoter/enhancer regions have been altered. PCR and sequence analysis showed that the CAV mutants were stable under cell culture conditions and Southern-blot analysis showed that all replication DNA intermediates were normally formed by the CAV mutants. All of the viable mutant strains were able to produce a neutralizing conformational epitope, implying that they can

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trigger the required protective immune response. Noteborn et al suggest the use of their mutant strains for the development of attenuated vaccines against CAV.

Chicken anemia virus is a member of the family Circoviridae (see the teachings of U.S. Patent No. 6,287,856 above). Encapsulation of the mutated CAV genomes would necessarily be expected to result in compaction of the DNA due to the normal effects of DNA packaging. Further, one necessarily expect that not all of the circovirus proteins are equally antigenic. Thus, it is reasonable to expect that the inclusion of more than one viral protein in the compositions taught by Noteborn et al would encompass embodiments where one protein increases the antigenic response as compared to the same construct not expressing that protein.

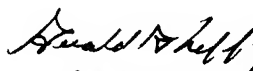
### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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